## **CLAIMS AS AMENDED:**

- 1. (Currently Amended) A method of determining the *initial dose* of a *vitamin* D compound [[,]] for the treatment of secondary hyperparathyroidism and renal osteodystrophy without increasing the incidence of hypercalcemia comprising:
  - a) measuring a patient baseline PTH (bPTH) value,
  - b) determining [[the]] <u>a final dose of the vitamin D compound, where the final dose is that dose associated with a first stable clinically significant reduction in patient intact parathyroid hormone (PTH) for the vitamin D compound,</u>
  - c) Applying the baseline PTH value and final dose to regression analysis, and
  - d) calculating the initial dose of the vitamin D compound from the regression analysis of step c.
- 2. (Currently Amended) The method of claim 1 wherein the [linear model] regression analysis is a zero intercept linear model.
- 3. (Original) The method of claim 1 wherein the vitamin D compound is a vitamin D<sub>2</sub> compound.
- 4. (Original) The method of claim 3 wherein the vitamin D<sub>2</sub> compound is paricalcitol.
- 5. (Currently Amended) The method of claim 4 wherein the initial dose is patient baseline PTH/80 (bPTH/80).
- 6. (Currently Amended) [[The]]\_method of treating secondary

  hyperparathyroidism and renal dystrophy using a vitamin D compound without
  increasing the incidence of hypercalcemia [[claim 1 further]] comprising
  - a) measuring a patient baseline PTH value;

- b) determining a final dose of the vitamin D compound associated with a first stable clinically significant reduction in patient PTH for the vitamin D compound;
  - c) applying the baseline PTH and final dose to regression analysis;
- d) calculating the initial dose of the vitamin D compound from the regression analysis of step c; and
- e) [[administration of]] administering the initial dose determined in step d to the patient.
- 7. (Currently Amended) A method of treating elevated <u>intact parathyroid</u> <u>hormone</u> (PTH) in a patient commencing treatment for [[ESRD]] <u>end stage renal</u> <u>disease</u>, the method comprising:
  - a) determining the initial dose of a vitamin D compound from a regression analysis based on a patient baseline PTH (bPTH) and a final dose of the vitamin D compound associated with a first stable and clinically significant reduction in patient PTH for the vitamin D compound, and
  - b) administering the initial dose of the vitamin D compound <u>determined in</u> <u>step a</u> to the patient.
- 8. (Original) The method of claim 7 wherein the vitamin D compound is paricalcitol.
- 9. (Currently Amended) The method of claim 8 wherein the initial dose is about patient baseline parathyroid hormone/80 (bPTH/80).
- 10. (Currently Amended) A method of treating a patient [undergoing vitamin D therapy] for end stage renal disease [[ESRD]] using a vitamin D therapy. [[wherein the]] comprising administering an initial dose of vitamin D [[administered]] to the patient wherein the initial dose of vitamin D is about patient baseline parathyroid hormone/80 (bPTH/80) and bPTH is the baseline PTH for the patient.

- 11. (Currently Amended) A method of treating a patient [undergoing vitamin D therapy] for secondary hyperparathyroidism <u>using a vitamin D therapy</u>, [wherein the] <u>comprising administering an</u> initial dose <u>of vitamin D</u> [administered] to the patient <u>wherein the initial dose of vitamin D</u> is about <u>patient baseline parathyroid</u> <u>hormone/80 (bPTH/80) and bPTH is the baseline PTH for the patient.</u>
- 12. (Currently Amended) A method of <u>determining the initial dose of a vitamin</u> <u>D compound</u> using a zero-intercept linear regression model [to determine the initial dose of a vitamin D compound].
- 13. (Currently Amended) A method of treating a patient undergoing vitamin D therapy for [[ESRD]] end stage renal disease wherein a zero-intercept regression model is used to determine the initial dose of the vitamin D compound.
- 14. (Currently Amended) The method of claim 13, wherein the vitamin D therapy [[the vitamin D compound]] results in the prevention or treatment of renal osteodystrophy or secondary hyperparathyroidism.
- 15. (Original) A method of claim 8 wherein the initial dose is at least 1 mcg.
- 16. (New) The method of claim 13, wherein the vitamin D therapy does not increase the incidence of hypercalcemia.